DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 2, 2016

Limacorporate S.p.A.
% Ms. Cheryl Hastings
Hastings Regulatory Consulting, LLC
P.O. Box 696
Winona Lake, Indiana 46590-696

Re: K113254
Trade/Device Name: SMR Modular Glenoid
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: February 21, 2012
Received: February 22, 2012

Dear Ms. Hastings:

This letter corrects our substantially equivalent letter of February 24, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): Unknown
Device Name: SMR Modular Glenoid
Indications for Use:

SMR Modular Glenoid
Indications for Use

The SMR Modular Glenoid is intended for use in total primary or revision shoulder joint replacement with either the SMR Anatomic Shoulder System or the SMR Reverse Shoulder system.

The SMR Anatomic Shoulder System is indicated for patients suffering from disability due to:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Inflammatory degenerative joint disease such as rheumatoid arthritis;
- Treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods;
- Revision of a failed primary implant;
- Cuff tear arthropathy (CTA Heads only);

In the US, the SMR Metal Backed Glenoid/Liner construct, used as part of the SMR Anatomic Shoulder Replacement, is intended for use with bone cement and should be used without bone screws.

The SMR Reverse Shoulder System is indicated for primary, fracture or revision total shoulder replacement in a grossly rotator cuff deficient joint with severe arthropathy (disabling shoulder). The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The SMR Metal Backed Glenoid/Connector/Glenosphere construct, used as part of the SMR Reverse Shoulder replacement, is intended for uncemented use with the addition of screws for fixation.

Prescription Use X	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A. Millers

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113254

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Summary of Safety and Effectiveness

Date: October 27, 2011

Manufacturer:
Limacorporate S.p.A.
Via Nazionale, 52
33038 – Villanova di San Daniele
Udine - Italy

U.S. Contact Person:
Cheryl Hastings
Principal Consultant
Phone: 574-527-4220

Product	Product Code	Regulation and Classification Name
SMR Modular Glenoid	KWS	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660

Description:

The SMR Modular Glenoid consists of a metal-back and a liner; when used without cement, bone screws are used for additional fixation. These components are used in total shoulder replacements: the SMR Modular Glenoid metal-backs can be used either in anatomical replacement (when coupled with SMR Modular Glenoid liners) or in reverse replacement (when coupled with previously cleared glenospheres and connectors). The SMR Metal Backed Glenoid and Liner construct, when used as part of a SMR Anatomic Shoulder Replacement is intended for use with bone cement and should be used without bone screws. The SMR Metal Backed Glenoid, Connector and Glenosphere construct, when used as part of a SMR Reverse Shoulder Replacement is intended for uncemented use with the addition of screws for fixation. The size large metal back is not suitable for coupling with 36 mm concentric glenosphere.

Metal-backed glenoids are made from Ti6Al4V. The backside surface of the metal-back is plasma spray titanium coated. Four sizes (small-R, Small, Standard and Large) are available.

Liners are manufactured from UHMWPE. In anatomical replacement, these devices are intended to be coupled with the SMR Modular Glenoid metal-backs and articulate with previously cleared SMR standard or CTA humeral heads. Liners are available in four sizes (small-R, Small, Standard and Large).

The liner articulating surface has a radius of curvature greater than the corresponding humeral head allowing translation in the superior/inferior and anterior/posterior directions. The SMR system has no restriction in regard to the pairing of different sizes of humeral heads and glenoid components. Each humeral head size can be combined with each glenoid size.

Bone screws are manufactured from titanium alloy Ti6Al4V (ASTM F1472 – ISO 5832-3). Bone screws have a diameter of 6.5 mm and are available in lengths from 20 to 40 mm.

Intended Use:

The SMR Modular Glenoid is intended for use in total primary or revision shoulder joint replacement with either the SMR Anatomic Shoulder System or the SMR Reverse Shoulder system.

The SMR Anatomic Shoulder System is indicated for patients suffering from disability due to:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Inflammatory degenerative joint disease such as rheumatoid arthritis;
- Treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods;
- Revision of a failed primary implant;
- Cuff tear arthropathy (CTA Heads only);

In the US, the SMR Metal Backed Glenoid/Liner construct, used as part of the SMR Anatomic Shoulder Replacement, is intended for use with bone cement and should be used without bone screws.

The SMR Reverse Shoulder System is indicated for primary, fracture or revision total shoulder replacement in a grossly rotator cuff deficient joint with severe arthropathy (disabling shoulder). The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The SMR Metal Backed Glenoid/Connector/Glenosphere construct, used as part of the SMR Reverse Shoulder replacement, is intended for uncemented use with the addition of screws for fixation.

Predicate Devices:

SMR Reverse Shoulder System metal-back glenoid (Limacorporate, K110598);
SMR Shoulder System (Limacorporate, K100858);
SMR Uncemented Shoulder System (Limacorporate, K101263);
SMR CTA Humeral Heads (Limacorporate, K110847);
SMR Revision Stems (Limacorporate, K111212);
Bio-modular Shoulder System (Biomet, K030710, K992119);
Metal-backed Revision Glenoid (Encore - DJO, K081448).

Comparable Features to Predicate Device(s): The SMR Modular Glenoid is similar to the predicate devices in terms of intended use, indications, design and materials. The

SMR Modular Glenoid and the predicates are all intended for total primary or revision shoulder joint replacement. The metal-backs are plasma spray coated. Fixation methods for the SMR Modular Glenoid depend on whether it is being used with an Anatomic or Reverse Shoulder System. These fixation methods are similar to those for the predicate Anatomic and Reverse Shoulder Systems.

The metal-back glenoid of the SMR Modular Glenoid system has a design which is similar to the metal-back glenoid used for the SMR Reverse Shoulder System (K110598): the only difference is the addition of four lugs to allow the same metal back glenoid to be used with either the SMR Anatomic Shoulder or with the SMR Reverse Shoulder. Like the Bio-modular Shoulder System (Biomet), the liner-metal back coupling is achieved through a snap-fit junction.
The components of the SMR Modular Glenoid are manufactured from the same or similar materials as the predicate devices.

Non-Clinical Testing: The SMR Modular Glenoid was tested in static shear and dynamic testing. The plasma spray titanium coating was tested in adhesion, shear, shear fatigue and abrasion testing. A Range of Motion simulation has been performed to ensure the device design does not overly limit range of motion. All mechanical testing was done on worst case components or constructs. Where possible, standard test methods were used to allow comparison to testing of the predicate devices. The testing results demonstrated the device's ability to perform under expected clinical conditions.

Clinical Testing: Clinical testing was not necessary to demonstrate substantial equivalence of the SMR Modular Glenoid to the predicate devices.